

- (b) screening the resulting transfected somatic cells *in vitro* to select a cell, wherein the selected cell is stably transfected with the DNA sequence by integration of the DNA sequence into the chromosome of the selected cell or in a replication competent plasmid to impart to the selected cell the permanent capacity to direct expression of the DNA sequence;
- (c) cloning and expanding the selected somatic cell *in vitro*; and
- (d) injecting the resulting cloned and expanded cells into the recipient subject; wherein the DNA sequence comprises the gene and a promoter[, wherein the promoter is not a retroviral promoter] capable of functioning in the somatic cells; and wherein, following injection of the clonal cells into the recipient subject, [the clonal cells are incapable of causing recombination of] the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

104. (Amended) A method of [for] transferring a gene into a recipient subject, comprising:

- (a) providing somatic cells;
- (b) transfecting said somatic cells *in vitro* with a DNA sequence comprising said gene and a promoter capable of functioning in said somatic cells, wherein said gene encodes a gene product, and wherein said somatic cells are stably transfected with said gene by integration of the gene into the chromosomes of the somatic cells or in

100-12900
99 DEC / 3 AM 10:55
TECH DEPT REC'D 12/29/99

LAW OFFICES

FINNEGAN, HENDERSON,
FARABOW, GARRETT,
& DUNNER, L.L.P.
1300 I STREET, N.W.
WASHINGTON, DC 20005
202-408-4000

replication competent extrachromosomal plasmids to impart to said somatic cells the permanent capacity to direct expression of said gene upon induction of said promoter;

- (c) screening the resulting transfected somatic cells *in vitro* to select a transfected somatic cell, wherein said screening comprises characterizing said transfected somatic cell with respect to expression and regulation of the gene by assaying for translation of the mRNA into the gene product;
- (d) cloning and expanding, *in vitro*, the transfected somatic cell selected in step (c) to form said 10^5 - 10^{10} transfected somatic cells, and
- (e) combining the 10^5 - 10^{10} transfected somatic cells with a physiologically acceptable buffer or carrier; and
- (f) injecting the resulting transfected cell preparation into the recipient subject, wherein, following injection of the clonal cells into the recipient subject, [the clonal cells are incapable of causing recombination of] the DNA sequence is incapable of recombining with endogenous retroviral sequences, and the DNA sequence is incapable of initiating chronic viral infection in the recipient subject.

REMARKS

Applicant has amended claims 72 and 104 to further define the claimed invention. Upon entry of this amendment, claims 72-79, 82-84, and 104-106 will be pending in this application.

Applicant thanks the Examiner for the courtesy of the telephonic interview with the undersigned on December 2, 1999. Although the schedules of the parties who